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RESPIRONICS



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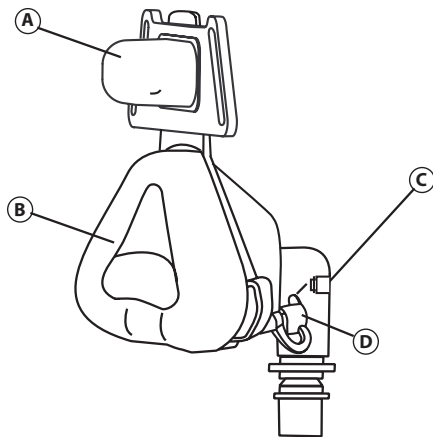
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Profile Lite
INSTRUCTIONS FOR USE

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ProfileLite Nasal Gel Mask



◀ Figure 1

A = Gel Forehead Spacer

B = Mask Cushion

C = Exhalation Port

(Do not block)

D = Removable Port Cap

**CAUTION**

US federal law restricts this device to sale by or on the order of a physician.

Intended Use

The Profile Lite Nasal Gel Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.



Important Note: An exhalation port is built into the Profile Lite Nasal Gel Mask so a separate exhalation port is not required.

Warnings:

- This mask is not suitable for providing life support ventilation.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. **Do not block or try to seal the exhalation port. Explanation of the Warning:** CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. This warning applies to most models of CPAP systems. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is



Warning

A warning indicates the possibility of injury to the user or operator.



Caution

A caution indicates the possibility of damage to the device.









Note

A note places an emphasis on an operating characteristic.

not operating. **Explanation of the Warning:** When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.

- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- At low CPAP or EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- If an additional exhalation device is added to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.
- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears or cushion damage resulting in gel exposure, etc). Discard and replace any components as necessary.
- Carefully touch the mask cushion to be sure that it has cooled enough to prevent irritation or burning.
- Use of a nasal or full face mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.

Symbols

Symbol	Description
	General Caution or Warning
	Consult instructions for use
	System One Resistance Control
	Note
	Tip
	Does not contain natural rubber latex

Cleaning Instructions

Hand wash the mask before first use and daily. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

1. Hand wash the mask and headgear in warm water with a mild liquid dish washing detergent.




Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

2. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

For **multi-patient use** in the hospital/institutional environment, use the Mask Cleaning and Disinfection Instructions to reprocess the mask between patients. These instructions can be obtained by visiting www.sleepapnea.com or contacting Respirationics Customer Service at 1-800-345-6443 (USA or Canada) or 1-724-387-4000.

System One Resistance Control

This mask uses the System One Resistance Control setting  ← X1. This symbol may appear on your therapy device. This symbol represents the level of mask resistance compensation. Match the setting to the mask if appropriate.

Important Notes:

- Verify the System One setting if the mask or mask cushion changes.
- The System One setting is not compatible with masks requiring a separate/ additional exhalation device.

If your provider has locked the resistance compensation setting, you can view the setting but cannot change it, and the screen will display a lock symbol. If your provider has disabled the resistance compensation, you will not see this setting.

Putting on the Mask and Headgear

1. Hold the mask lightly against your face, and slide the headstrap over your head (Figure 2).
2. Connect the flexible tubing to the

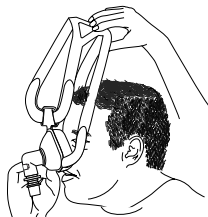



 Figure 2

exhalation elbow. Turn the CPAP or bi-level system on.

3. Lie down and breathe normally through your nose, keeping your lips closed. Unhook the straps and gradually tighten them until the mask has minimal leaks and fits comfortably.

 **Note:** The headstrap has two sets of tabs for better adjustment. For larger size heads, use the black tabs. For smaller head sizes, use the blue tabs (Figure 3). The extra tabs can be removed using a pair of scissors.

4. DO NOT overtighten the straps. Overtightening can cause or worsen leaks.

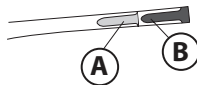


 Figure 3

*A = Use blue tabs for
smaller sized heads
B = Use black tabs for
larger sized heads*

Removing the Mask and Headstrap

Because the entire headstrap stretches, you should not need to unfasten the straps to remove the headstrap. Simply slide the mask and headstrap over your head. If necessary, unfasten either of the neck straps.

Replacing the Gel Spacer

Replace the gel spacer if it is punctured, leaking or damaged. See the last page of these instructions for order information.

Before attaching a new gel spacer, remove the headgear from the mask following the instructions below. Slide the top tabs (1) on the gel spacer into the top headgear slot (Figure 4), then attach the bottom tabs (2) on the gel spacer into the bottom headgear slot.

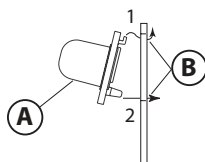


Figure 4

A = Gel spacer

B = Headgear slots

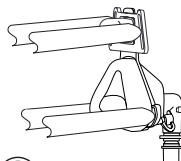


Figure 5

Reforming the Mask

OPTIONAL: If you are not able to minimize leaks, you may want to reform the mask to fit your face more closely.

1. Remove the headstrap and spacer from the mask (Figure 5 and Figure 6). Fill a container with enough water to cover the entire mask. (DO NOT put the mask in the water at this time.) Place the container over heat and bring the water to a boil. Remove the container from the heat.

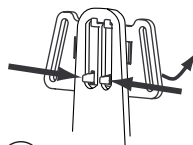
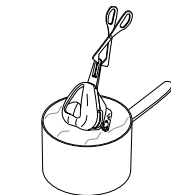


Figure 6

⚠ Caution: Do not heat the mask by placing it into the microwave or conventional oven. The mask will be damaged.

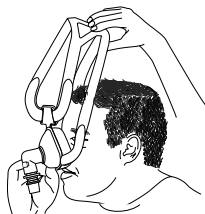
2. Using tongs or a similar utensil, slowly place the mask into the water being careful to keep the water from spilling over (Figure 7). Soak the mask for four minutes. Using the tongs again, grab the mask at the extension and remove it from the water. Place the mask in cold water for ten seconds. Reconnect the spacer and headstrap.



▲ Figure 7

⚠ Warning: Before placing the mask on your face, be sure the mask has cooled enough to prevent irritation or burning.

3. Place the mask on your face in the position you will be wearing it, pressing comfortably against your face (Figure 8). Slide the headgear over your head.



▲ Figure 8

≡ Note: Be sure to tighten the headgear to the tension you would normally use. Wear the mask and headgear for five minutes to allow the mask to form to your face. Remove the mask and headstrap. The mask will maintain its shape.

≡ Note: The mask can be reformed, if necessary, by repeating steps 1 through 3.


Comfort Tips

- Clean your face and mask thoroughly before each use.
- Make sure the mask is the correct size for your face.
- Do not overtighten the headgear. Overtightening can irritate your face, increase leaks, or cause damage to the mask.
- Replace the cushion and forehead gel spacer if they become hardened or deformed.

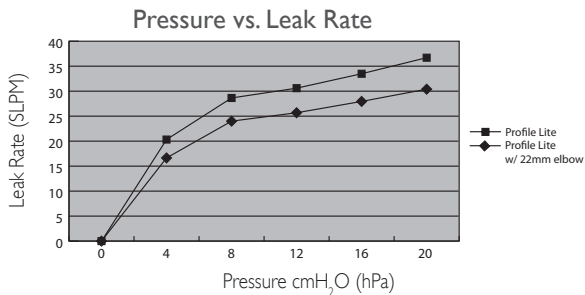
Disposal

Dispose of in accordance with local regulations.

Specifications

 **Warning:** The technical specifications of the mask are provided for your clinician to check that they are compatible with the CPAP or bi-level device. If used outside specification or if used with incompatible devices, the seal and comfort of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect the CPAP or bi-level device function.

Intentional Leak



Pressure Drop cm H₂O (hPa)

	50 SLPM	100 SLPM
Large	0.1	0.3

Deadspace

≤ 281 cc.

Storage Conditions

Temperature -4° F to 140° F (-20° C to 60° C)

15% to 95% RH, non-condensing

LIMITED WARRANTY

Respironics, Inc. warrants that its mask systems (including mask frame and cushion) (the "Product") shall be free from defects of workmanship and materials for a period of ninety (90) days from the date of purchase (the "Warranty Period").

If the Product fails under normal conditions of use during the Warranty Period and the Product is returned to Respironics within the Warranty Period, Respironics will replace the Product. This warranty is non-transferable and only applies to the original owner of the Product. The foregoing replacement remedy will be the sole remedy for breach of the foregoing warranty. This warranty does not cover damage caused by accident, misuse, abuse, negligence, alteration, failure to use or maintain the Product under conditions of normal use and in accordance with the terms of the product literature, and other defects not related to materials or workmanship. This warranty does not apply to any Product that may have been repaired or altered by anyone other than Respironics.

Respironics disclaims all liability for economic loss, loss of profits, overhead, or indirect, consequential, special or incidental damages which may be claimed to arise from any sale or use of the Product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS SPECIFICALLY DISCLAIMED. SOME STATES DO NOT ALLOW DISCLAIMERS OF IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE.

To exercise your rights under this limited warranty, contact your local authorized Respironics, Inc. dealer or Respironics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

Reorder Information

1002849	Profile Lite Mask, P
1002850	Profile Lite Mask, S
1002370	Profile Lite Mask, MS
1002371	Profile Lite Mask, M
1002372	Profile Lite Mask, MW
1002374	Profile Lite Mask, LN
1002373	Profile Lite Mask, L
1004292	Gel Retrofit Spacers, S
1004291	Gel Retrofit Spacers, L
1008869	Gel Retrofit Spacers, XL
1004086	Profile Lite Mask w/headstrap, P
1004087	Profile Lite Mask w/headstrap, S
1004088	Profile Lite Mask w/headstrap, MS
1004089	Profile Lite Mask w/headstrap, M
1004110	Profile Lite Mask w/headstrap, MW
1004112	Profile Lite Mask w/headstrap, LN
1004111	Profile Lite Mask w/headstrap, L
1004395	Exhalation Elbow Kit
1002720	Split Washer Kit (5 ea.)
7041	Mask Swivel

For a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 (US or Canada only) or 724-387-4000 to obtain a product catalog (#1027825) or visit us online at www.sleepapnea.com.